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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,869	05/08/2002	James Michael Rini	12243.23USWO	8589

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EXAMINER	
PRATS, FRANCISCO CHANDLER	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 08/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/018,869	RINI ET AL.	
	Examiner	Art Unit	
	Francisco C. Prats	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *11-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5-8-02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-35 are presented for examination.

Election/Restrictions

Applicant's election with traverse of the group I, invention, claims 1-10, in the reply filed on June 13, 2005, is acknowledged. The traversal is on the ground(s) that the inventions are not distinct, that a 12-way restriction is improper, and that the invention I can be searched and examined with the other pending claims. This is not found persuasive because the various inventions are considered distinct for the reasons set forth in the original restriction requirement. Also, under lack of unity rules, the various claimed inventions also clearly lack a common technical feature which defines them over the prior art, as demonstrated by the amount of prior art applicable to the claims herein. Moreover, as to the issue of distinctness, applicant has failed to demonstrate, or admit for the record, that any of the inventions would necessarily be obvious over any of the other inventions.

The requirement is still deemed proper and is therefore made FINAL.

Claims 11-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. As discussed immediately above, applicant timely traversed the restriction (election) requirement in the reply filed on June 13, 2005.

Claims 1-10 are examined on the merits.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-10 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, the claims recite the "structure of a purified glycosyltransferase." However, the structure of an enzyme, even when purified, is an inherent property of the enzyme, and therefore is a naturally occurring phenomenon. A naturally occurring phenomenon is not patentable subject matter.

Also, a "structure" reads on a formula or informational representation of the enzyme molecule. This structural information is not a composition of matter, but rather a

representation thereof. For example, one may patent an enabled, novel and non-obvious chemical compound. However, one may not patent the "formula" or "structure" of that compound.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, the claims encompass the structures of any and all glycosyltransferases meeting a specific set of structural requirements. Despite the great breadth of the claims rejected herein, the only glycosyltransferase structure for which applicant has demonstrated possession is the GnT I enzyme from rabbit. Applicant provides no suggestion that the

sole exemplified enzyme is representative of the genus of all glycosyltransferase enzymes, such that applicant can be considered to be in possession of all glycosyltransferase enzyme structures. Moreover, applicant fails to provide any descriptive information about any of the other glycosyltransferase enzymes which might possibly fall within the structural requirements set forth in the claims. Thus, because the as-filed specification fails to provide evidence that applicant was in possession of the full scope of the subject matter recited in the claims, rejection under the written description requirement is required.

Claims 1 and 6-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the GnT I enzyme from rabbit, does not reasonably provide enablement for any and all enzymes having the structural attributes recited in the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Specifically, the claims encompass the structures of any and all glycosyltransferases meeting a specific set of structural requirements. Despite the great breadth of the

claims rejected herein, the as-filed specification provides only one example, GnT I from rabbit, of a glycosyltransferase meeting the claimed structural requirements. The as-filed specification does not provide any guidance as to where any other glycosyltransferases meeting the claimed structural requirements can be obtained, how such enzymes may be purified or otherwise made, nor does the as-filed specification provide any suggestion as to the likelihood of finding any such enzyme. Thus, with the exception of the exemplified GnT I from rabbit, the artisan of ordinary skill seeking to practice the full scope of the rejected claims, would have to undertake an essentially trial and error process, with no guidance and no idea of the likelihood of success coming from the specification. Such a trial and error process clearly amounts to undue experimentation.

In sum, undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite because they claim the "structure" of a glycosyltransferase enzyme. It is unclear whether applicant seeks to encompass the enzyme itself, or just the structural properties of the enzyme. The scope of the recitation "structure" is therefore not clear, when applied to the context of its use.

Also, the recitation "a purified glycosyltransferase when it associates with a nucleotide sugar donor, acceptor, or metal cofactor" in claim 1 is indefinite. It is not clear what relationship between the enzyme and second-recited moiety is encompassed by the term "associates." The scope of the claims is unclear. Similarly, claim 2 is confusing in its recitation of a glycosyltransferase "in association" with a moiety. The scope of the relationship between the enzyme and the moiety is simply not clear.

In claim 6, the recitations "small" and "short" are indefinite because it is not clear how small or how short the moieties described by these recitations are.

In claims 8-10, it is unclear what the claims encompass. It is not clear how many, or which, of the structural coordinates from Tables 1-4 must be present in the structure of the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 are rejected under 35 U.S.C. 102(a) as being anticipated by Ünligil et al (Glycoconjugate Journal 17(1-2):15 (Jan-Feb 2000)) or Rini et al (Book of Abstracts, 219th ACS National Meeting, San Francisco, CA, March 26-30, 2000).

Each of Ünligil and Rini disclose the x-ray crystal structure of rabbit N-acetyglucosaminyl transferase I (GnT I). The references therefore clearly anticipate the claims. Note

that because the authoring entity of each of the published abstracts is different than the inventive entity of the application under examination herein, a holding of anticipation is required.

Claims 1-10 rejected under 35 U.S.C. 102(b) as being anticipated by Charnock et al (Biochemistry 38:6380-6385 (1999)).

Charnock discloses the crystalline structures, both native and metal/nucleotide donor-complexed, of Sps A, a glycosyltransferase from *Bacillus subtilis* admitted by applicant to possess "an identical topology, and all of the major structural elements" (specification, page 36, lines 7-8) characterizing the catalytic domain of the GnT I enzyme, the GnT I enzyme itself being admitted by applicant as possessing all of the claimed structural attributes. Because the Sps A enzyme possesses all of the structural attributes of the GnT I enzyme, and because the GnT I enzyme possesses all of the claimed structural attributes, a holding of anticipation over the cited claims is required.

Claims 1-3 and 5-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Sarkar et al (Glycoconjugate Journal 15:193-197 (1999)).

Sarkar discloses purified forms of rabbit GnT I, and assays thereof, in the presence of (i.e., associated with) the required donor sugar and or metal cofactors. See, e.g., abstract. Because the structure of the enzyme is an inherent property of the enzyme, the reference also discloses the enzyme's structure. A holding of anticipation is therefore required.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown et al (EMBO Journal 18(15):4096-4107 (1999)).

Brown discloses the crystalline structure of the enzyme, N-acetylglucosamine 1-phosphate uridyltransferase, in complexed form. See page 4098. Technically, the enzyme described in Brown is a GlcNAc transferase, inasmuch as the enzyme transfers GlcNAc-1-P on to a UDP moiety. A holding of anticipation is therefore required.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Gastinel et al (EMBO Journal 18(13):3546-3557

(1999)) or Vrielink et al (EMBO Journal 13(15):3413-3422 (1994)).

Each of the cited references discloses the x-ray crystal structure of a glycosyltransferase. See abstract, each reference. A holding of anticipation is therefore required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35

U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sarkar et al (Glycoconjugate Journal 15:193-197 (1999)) in view of Charnock et al (Biochemistry 38:6380-6385 (1999)), Brown et al (EMBO Journal 18(15):4096-4107 (1999)), Gastinel et al (EMBO Journal 18(13):3546-3557 (1999)) or Vrielink et al (EMBO Journal 13(15):3413-3422 (1994)).

As discussed above, Sarkar discloses the structure of GnT I. Sarkar differs from the claims under examination in that Sarkar does not disclose the preparation of GnT I in crystalline form as recited in claim 4, and possibly claims 8-10. However, each of Charnock (e.g., pages 6380-6381), Brown (e.g., page 4098, first paragraph, left column), Gastinel (page 3547, left column, third full paragraph), and Vrielink (page 3414, left column, second paragraph) discloses that crystallization is a useful method of studying glycosyltransferase structure, function, mechanism of action, as well as a method providing information suitable for designing drugs to affect the activities of those enzymes. Thus, one of ordinary skill seeking to study GnT I clearly would have been motivated by the advantages of crystallization in the Charnock, et seq., references, to have prepared Sarkar's GnT I enzyme in

crystalline form, for analytical purposes. A holding of obviousness over the cited references is therefore required.

No claims are allowed. The Ünligil et al (EMBO Journal 19(20):5269-5280 (2000)) reference is not prior art, but is cited to further show the state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C. Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Francisco C. Prats
Primary Examiner
Art Unit 1651

FCP